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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,667	03/08/2004	Omolayo O. Famodu	BB1191USCNT	2588

23906 7590 08/12/2005

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
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4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/796,667	FAMODU ET AL.
	Examiner	Art Unit
	Kagnew H. Gebreyesus	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 31-40 in part are drawn to an isolated polynucleotides encoding an amino acid sequence of a zea mays polypeptide (SEQ ID NO: 10), classified in class 536, subclass 23.2.

II. Claims 31-40 in part are drawn to an isolated polynucleotides encoding an amino acid sequence of a oryza sativa polypeptide (SEQ ID NO: 12), classified in 536, subclass 23.2.

III. Claims 31-40 in part are drawn to an isolated polynucleotides encoding an amino acid sequence of a glycine max polypeptide (SEQ ID NO: 14), classified in 536, subclass 23.2.

IV. Claims 41-43 in drawn to a method of producing a plant comprising transforming a plant cell with an isolated polynucleotides (SEQ ID NO: 9) encoding an amino acid sequence of a zea mays polypeptide, a plant and a seed transformed with said polynucleotide (SEQ ID NO: 9).

V. Claims 41-43 in drawn to a method of producing a plant comprising transforming a plant cell with an isolated polynucleotides (SEQ ID NO: 11) encoding an amino acid sequence of an oryza sativa polypeptide, a plant and a seed transformed with said polynucleotide (SEQ ID NO: 11).

VI. Claims 41-43 in drawn to a method of producing a plant comprising transforming a plant cell with an isolated polynucleotides (SEQ ID NO: 13) encoding an amino

acid sequence of a glycine max polypeptide, a plant and a seed transformed with said polynucleotide (SEQ ID NO: 13).

1. The inventions are distinct, each from the other because of the following reasons:

Groups I-III drawn to polynucleotide encoding cysteinyl tRNA synthetases from various plants. Each Group is classified identically. However, these Groups are distinct, each from the other, by virtue of their distinct structures. Each SEQ ID NO has a different structure that is unrelated, except via the function of the enzyme they encode, to the others. No consensus sequence describing the Groups is disclosed or claimed. Moreover, these enzymes as encoded by the polynucleotides from different sources are only described in the instant specification using their structures; in other words, these is no description of cysteinyl tRNA synthetases from plants having particular characteristics in common, such as pI, catalytic activity values, etc. Thus, each of these enzymes and the polynucleotides encoding them, as defined by their structures, is patentably distinct from the others. Moreover, a search of any two of the Groups would be undue considering not only the entirely distinct structure search that would not overlap whatsoever, but also the entirely distinct textual search in the non-patent literature which search would include the enzyme name and/or activity and the source. Thus, Groups I-III are patentably distinct, each from the other.

The inventions of Groups IV-VI are independent methods as they comprise different steps and/or utilize different products and/or yield different results. In addition the search and examination of each method in Groups IV-VI in one patent application would result in undue burden, since the searches for all the groups are not co-extensive, since the searches are in

different classifications, and involve different field of search. Each of the of the inventions requires a separate patent and non-patent literature search requiring a different text search for each group and thus co examination of the inventions in groups I-IX would be a serious burden on the examiner.

1. Inventions in Groups I-III are related to inventions in Groups IV-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used as a hybridization probe.

1. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. During a telephone conversation with attorney----- on July, 22, 2005 a provisional election was made with traverse to prosecute the invention of group I, claims 31-40. Affirmation

of this election must be made by applicant in replying to this Office action.. Claims 41-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

1. The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 09/352,990 filed on July 14, 1999 now USPN 6,255,090.

2. However, the instant application is not granted the benefit of priority for the U.S. Provisional Application No. 60/092,866 filed on July 15, 1998 because the instant application does not comply with the rules set out in 35 U.S.C. ə 119 (e): namely, because there are no common inventors between the instant application and the provisional application.

Objections to the Abstract

3. The abstract is objected to for not completely describing the disclosed subject matter. Amendment encompassing a brief description of the full scope of the subject matter is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 38 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Claim 38 is drawn to nucleic acid molecules comprising polynucleotides encoding fragments of SEQ ID NO:10 in the absence of functional language.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses a polynucleotide encoding the cysteinyl tRNA synthetase of SEQ ID NO: 10 and sequences having at least 80% or more sequence identity to SEQ ID NO: 10 having cysteinyl tRNA synthetase activity. However, the genus of a polynucleotide sequence with only 30 nucleotides has been fully described by nieither a repesentative sequence or a functional limitations. (i.e., used as a probe or amplification primer). The genus of the instant claims also contains polynucleotides within the sequence fragment limitations, but having different function. For this reason applicants have not described the

subject matter in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-33, 37-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated cysteinyl tRNA synthetase gene comprising a nucleotide sequence encoding a polypeptide of SEQ ID NO: 10 does not reasonably provide enablement for any gene encoding a polypeptide having a homology of only 80-90% identity to the cysteinyl tRNA synthetase of SEQ ID NO: 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 31-33, 37, 39 and 40 are so broad as to encompass any DNA encoding a polypeptide having 80-90% identity to the specific DNA of SEQ ID NO: 10. While claim 38 is so broad as to encompass this short stretch of sequence which would be found in a large number of unrelated sequences. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid sequences broadly encompassed by the claims. Since the nucleic acid sequence of a gene encoding the corresponding protein determines its structural and functional properties, predictability of which changes can be tolerated in the nucleic acid sequence and obtain the desired activity of the

encoded protein requires a knowledge of and guidance with regard to which nucleotide(s) in the DNA sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the nucleic acid structure relates to the function of the encoded protein. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of SEQ ID NO: 10, 12 and 14.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within the DNA sequence where nucleic acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility of the encoded protein(s) are limited in any gene and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein encoded by any gene to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of a cysteinyl tRNA synthetase gene with 80-90% identity to the cysteinyl tRNA synthetase encoded by SEQ ID NOS: 9 or any polynucleotide comprising 30 nucleotides of SEQ ID NO: 9 because the specification does **not** establish: (A) regions of the nucleic acid structure which may be modified without effecting activity of the encoded protein; (B) the general tolerance of cysteinyl tRNA synthetase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide residues in SEQ ID NO: 9 with an expectation of obtaining the desired biological function; and (D) the

specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including cysteinyl tRNA synthetase having a cysteinyl tRNA synthetase activity with an enormous number of nucleic acid modifications (upto 20%) of the cysteinyl tRNA synthetase of SEQ ID NOS: 10. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of a genes encoding a cysteinyl tRNA synthetase polypeptide having the desired biological characteristics (i. e. a cysteinyl tRNA synthetase activity) is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 38 is rejected under 35 U.S.C. 102(e) as being anticipated by Lalgudi *et al.* (USPAP US 2002/0013958). The instant claim is drawn to a polynucleotide containing at least

30 nucleotides of SEQ ID NO: 9. Lalgudi *et al.* teach polynucleotide sequences from corn, one of which (SEQ ID NO: 1857) shows 100% sequence identity to a 249 base pair region spanning nucleotide 1631-1879 of SEQ ID NO: 9. The earliest document disclosure from this reference is disclosed in the priority document 60/085,331 filed on May 12, 1998.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus PhD.

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600

Seq. from 10/796667

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Pro Ala Tyr Leu Ala Gln Ser Leu Gln Ser Tyr Lys Gln Met Ser Ile
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